REMARKS

Claims 10 and 14-19 are pending in this application. Claims 1-9 and 11-13 were previously cancelled without prejudice to or disclaimer of the underlying subject matter.

1. Restriction/Election

Applicants acknowledge the continued finality of the election requirement to a single nucleotide sequence, but maintain their traversal.

2. Claim Rejections – 35 U.S.C. § 101

Claims 10 and 14-19 remain rejected under 35 U.S.C. § 101 because the claimed invention allegedly lacks patentable utility. Office Action page 2. Applicants respectfully disagree with the Examiner.

The Examiner has acknowledged that the specification describes multiple utilities for the present invention, including "acquiring genes, determining polymorphisms, molecular tags, expression studies, mapping and so forth...." Office Action dated March 9, 2004 at page 3. However, the Examiner maintains that none of these utilities are "specific and substantial." Applicants respectfully disagree with this assertion.

It is well-established law that "when a properly claimed invention meets at least one stated objective, utility under § 101 is clearly shown." *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983). The instant specification discloses many utilities that satisfy this requirement. For example, the specification clearly discloses that the nucleic acid molecules of the present invention encode a transcription factor or fragment thereof. *See, e.g.*, specification at page 31, lines 2-6, page 32, lines 6-11, page 56, line 11 through page 62, line 9, page 160, line 11 through page 232, line 3, and Table A. The specification also explains the cellular role of the enzymes in transcription (*see, e.g.*, specification at page 3, line 10 through page 21, line

15). In addition, the specification also discloses the various families of transcription factors and their roles in different cellular processes. *See, e.g.,* specification at page 6, line 22 through page 21, line 15 and Table A. The specification describes the transcription factor or fragment thereof encoded by SEQ ID NO: 1 is a member of the homeobox transcription factor family of transcription factors. *See, e.g.*, specification at page 233, Table A. One of ordinary skill in the art would recognize that the claimed nucleic acid molecules have utility, for example, to modify expression of genes in plant cells involved in, for example, regulation of cell-to-cell communication or development upon reading the present specification. These utilities are immediately apparent for the claimed nucleic acid molecules without further research.

The Examiner maintains that the claimed nucleic acid molecules lack utility apparently because one would allegedly not be able to recognize an appropriate partial or full open reading frame for the claimed nucleic acid molecules. *See* Office Action mailed March 9, 2004 at page 3. However, one of ordinary skill in the art would clearly be able to ascertain these elements based on Applicants' disclosure (*see, e.g.,* specification at page 224, lines 6-12, Table A and the sequence listing) and tools available to practitioners in the art, *e.g.,* BLASTX. Furthermore, neither a partial nor a full open reading frame is necessary to use the claimed nucleic acid molecules for the disclosed utilities, for example, as probes, to detect the presence or absence of polymorphisms, and in cosuppression/antisense applications.

Other utilities disclosed in the specification include the use of the claimed nucleic acid molecule in genetic mapping. Specification at page 84, line 4, through page 89, line 2. Another one of the utilities disclosed in the specification is use of the claimed nucleic acid molecules to identify the presence or absence of a polymorphism. Specification at page 76, line 11 through page 84, line 3. Further uses of the claimed nucleic acid

molecules are provided for at page 73, *et. seq.*, under the heading "Uses of the Agents of the Invention."

Applicants maintain that many of these uses are directly analogous to the use of a microscope. An important utility of a microscope resides in its use to identify and characterize the structure of biological tissues in a sample, cell, or organism. Significantly, the utility of a microscope under 35 U.S.C. § 101 is not compromised by its use as a tool in this manner. Many of the presently disclosed utilities are directly analogous to the utilities of a microscope, *i.e.*, the claimed nucleic acid molecules may be used to identify and characterize nucleic acid molecules within a sample, cell, or organism. Such utility is indistinguishable from the legally sufficient utility of a microscope. Thus, the presently disclosed sequences possess the requisite utility under 35 U.S.C. § 101.

In the Office Action, the Examiner attempts to undermine the existing utilities by maintaining that they are generally applicable to any nucleic acid. Office Action at pages 3. In short, the Examiner suggests that the asserted utilities are legally insufficient simply because other molecules can be used for the same purpose. Initially, Applicants submit that the use to encode a transcription factor or fragment thereof is not a use that is generally applicable to any nucleic acid. Moreover, the Examiner's position is wrong as a matter of law – there is no requirement of exclusive utility in the patent law. *See Carl Zeiss Stiftung v. Renshaw PLC,* 945 F.2d 1173, 1180, 20 U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991) ("An invention need not be the best or the only way to accomplish a certain result...").

Such an argument implies that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.*, hitting golf balls. Such a result is not only untenable, but requires reading "into the patent laws limitations and conditions which the legislature has not expressed," a practice condemned by the Supreme Court.

See Diamond v. Chakrabarty, 447 U.S. 303, 308, 206 U.S.P.Q. 193, 196 (1980), *quoting United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199, 17 U.S.P.Q. 154, 162 (1933). Thus, it must be the case that a utility, generic to a broad class of molecules, does not compromise the specific utility of an individual member of that class.

Applicants note that the claimed nucleic acid molecules encompass many utilities. Some of these utilities may be common to a broader class of molecules. For instance, nucleic acid sequences may generally be used to identify and isolate related sequences. However, when used in this manner, the result is not generic. Rather, the claimed nucleic acid molecules will identify a ***unique*** subset of related sequences. This subset of related sequences is specific to the claimed sequence and cannot be identified by any generic nucleic acid molecule. For example, a random nucleic acid molecule would not provide this specific utility. Referring again to the golf club analogy, the club is still generically hitting a golf ball, but is uniquely designed to hit the ball in a manner that is distinct from other clubs. Once again, Applicants assert that the claimed nucleic acid molecules exhibit the requisite utility under 35 U.S.C. § 101.

The Examiner has not provided any evidence that would reasonably suggest that the claimed nucleic acids cannot be used for the aforementioned utilities, and therefore has not met the burden of proof required to establish a utility rejection. *See In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). *Accord In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975); *In re Langer*, 503 F.2d 1380, 1391, 183 U.S.P.Q. 288, 297 (C.C.P.A. 1974). In fact, the Examiner has provided no evidence challenging the disclosed utilities for the presently claimed nucleic acid molecules. The Examiner "must do more than merely question operability - [she] must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975) (emphasis in original); MPEP § 706.03(a)(1) ("Office

personnel are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided..."). In the Office Action, the Examiner again provides no evidence challenging the disclosed utilities for the presently claimed nucleic acid molecules.

The Examiner further has not assessed the credibility of the presently asserted utilities. Credibility is precisely the issue that the courts have emphasized in evaluating the adequacy of an asserted utility. Utility is determined "by reference to, and a factual analysis of, the disclosure of the application." *In re Ziegler*, 992 F.2d 1197, 1201, 26 U.S.P.Q.2d 1600, 1603 (Fed. Cir. 1993), *quoting Cross v. Iizuka*, 753 F.2d 1040, 1044, 224 U.S.P.Q. 739, 742 (Fed. Cir. 1985). The Examiner "has the initial burden of challenging a presumptively correct assertion of utility in the disclosure." *In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). The utilities asserted in the specification must be accepted as factually sound unless the Patent Office cites information that undermines the credibility of the assertion. *Id.* As previously stated, the Examiner "must do more than merely question operability – [she] must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert,* 524 F.2d 1222, 1224-25, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975) (emphasis in original); MPEP § 706.03(a)(1) ("Office personal are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided..."). Here, the Examiner has not even attempted to meet this burden.

In view of the above, Applicants contend that the claimed nucleic acid molecules are supported by credible, specific, and substantial utilities disclosed in the specification. Moreover, the Examiner has failed to raise any credible evidence challenging the presently asserted utilities. Consequently, the rejection of claims 10 and 14-19 under 35

U.S.C. §101 is improper. Reconsideration and withdrawal of this rejection are respectfully requested.

3. Claim Rejections – 35 U.S.C. § 112, first paragraph, enablement

Claims 10 and 14-19 were rejected under 35 U.S.C. § 112, first paragraph, as not being enabled by the specification, because the claimed invention allegedly lacks utility (*i.e.*, an invention with no utility cannot be enabled). Applicants respectfully traverse this rejection, and note that this rejection has been overcome by the foregoing arguments regarding utility. Thus, the enablement rejection under 35 U.S.C. § 112, first paragraph, is improper. Reconsideration and withdrawal are respectfully requested.

4. Rejection Under 35 U.S.C. §112, 1st Paragraph: Written Description

The Examiner has rejected claims 10 and 14-19[1] under 35 U.S.C. § 112, first paragraph, for allegedly lacking an adequate written description. Office Action at page 4. The Examiner provides no new arguments. Applicants respectfully disagree with this rejection and reiterate their arguments below.

Although the Examiner has acknowledged that the specification discloses SEQ ID NO: 1, claims 10 and 14-19 allegedly fail to meet the written description requirement because the claims "encompass gene sequences and fragments of sequences of SEQ ID NO: 1, corresponding sequences from other species, mutated fragment sequences, allelic variants, splice variants, sequences which hybridize and so forth." Office Action mailed March 9, 2004 at page 7. Applicants respectfully disagree with this contention.

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[1] Claims 10-12 and 15-18 were previously rejected by the Examiner under 35 U.S.C. § 112, first paragraph. *See*, Office Action mailed March 9, 2004 at page 7. The Examiner has previously admitted that "SEQ ID NO: 1 per se meets the written description and enablement provisions of 35 U.S.C. § 112, first paragraph." *Id.* at page 8. It appears that the Examiner has changed the rejection to include claims 14 and 19, however, the Examiner has not provided any arguments why these claims do not meet the written description requirements.

As argued previously, an adequate written description of a genus of nucleic acids, as recited in claims 10 and 15-18, as well as claims 14 and 19, may be achieved by either "a recitation of a representative number of [nucleic acid molecules], defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus." *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69 (Fed. Cir. 1997). The feature relied upon to describe the claimed genus must be capable of distinguishing members of the claimed genus from non-members. *Id.*

The purpose of the written description requirement is to ensure that the inventors had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). In accordance with this purpose, Applicants need not "describe," in the sense of Section 112, all things that are encompassed by the claims. To contend otherwise would contradict established jurisprudence, which teaches that a patent may be infringed by technology developed after a patent issues. *United States Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247, 1251, 9 U.S.P.Q.2d 1461, 1464 (Fed. Cir. 1989). A related, and equally well-established principle of patent law is that claims "may be broader than the specific embodiment disclosed in a specification." *Ralston Purina Co. v. Far-mor-Co*, 772 F.2d 1570, 1575, 227 U.S.P.Q. 177, 179 (Fed. Cir. 1985), *quoting In re Rasmussen*, 650 F.2d 1212, 1215, 211 U.S.P.Q. 323, 326 (C.C.P.A. 1981). Thus, in order for Applicants to describe each and every molecule encompassed by the claims, it is not required that every aspect of those nucleic acid molecules (*e.g.*, an open reading frame) be disclosed. *In re Alton,* 76 F.3d 1168, 1175 (Fed. Cir. 1996) (if a person of ordinary skill in the art would have understood the

inventor to have been in possession of the claimed invention at the time of filing even if every nuance of the claims is not explicitly described in the specification).

It is well-settled law that each nucleic acid molecule within a claimed genus does not need to be described by its complete structure. The Federal Circuit has elucidated a test for written description wherein a genus of nucleic acids may be described by a structural feature that distinguishes members of the claimed genus from non-members of the claimed genus. *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997). In contrast to the mere name "cDNA" provided in *Eli Lilly*, Applicants have provided a detailed chemical structure by way of the claimed SEQ ID NO: 1. Applicants have therefore satisfied the *Eli Lilly* test for written description.

Applicants have provided a detailed chemical structure, *i.e.*, the nucleic acid sequence of SEQ ID NO: 1. Nucleic acid molecules falling within the scope of claims 10 and 15-18 are readily identifiable – they comprise a nucleic acid molecule having the nucleic acid sequence of SEQ ID NO: 1 or variation thereof. The fact that the nucleic acid molecules may comprise additional sequences or variations is beside the point. Such modifications are readily envisioned by one of ordinary skill in the art and disclosed through the present specification. Thus, there is no deficiency in the written description support for the claimed invention. Therefore, claims 10 and 14-19 satisfy the written description requirement of 35 U.S.C. § 112, first paragraph. Reconsideration and withdrawal of this rejection are respectfully requested.

5. Claim Rejections – 35 U.S.C. § 112, second paragraph

Claims 15-19 stand rejected under 35 U.S.C. § 112, second paragraph, for purportedly being indefinite. Office Action at page 5. Applicants respectfully disagree. Applicants respectfully point out that the claims are to be read in light of the

specification. *See in re Vogel*, 422 F.2d 438, 441, 164 U.S.P.Q. 619, 622 (C.C.P.A. 1970). The test for determining whether terms in a given claim are indefinite is whether one skilled in the art would understand what is claimed. *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991), *cert denied,* 112 S.Ct. 169 (1991). A person of ordinary skill in the art would understand the metes and bounds of the claims read in light of the disclosure of the specification.

The Examiner alleges that claims 15-19 are unclear as to the meaning of the term "share" in the phrase "nucleic acid sequence shares between...." In particular, the Examiner argues that "[a]s share can mean to divide and distribute, to have in common, or to use partially," the claims are unclear. Applicants disagree. It is submitted that the recitation of "shares" in the claims is definite when read in light of the specification. *See, e.g.*, specification at page 55, lines 9-23. As such, Applicants respectfully submit that the term "share" is definite when read in light of the specification.

The Examiner also suggests that claims 15-19 are "unclear as to the intended meaning, the instant claims read on fragments of SEQ ID NO: 1." Office Action at page 5. Applicants respectfully point out that as claims 15-19 do not recite the term "fragment," the skilled artisan would readily understand the scope of the claims. As such, Applicants respectfully submit that the claims are definite.

As such, Applicants respectfully request withdrawal of these rejections under 35 U.S.C. § 112, second paragraph.

6. Claim Rejections – 35 U.S.C. § 102 (a) and (b)

Claims 15-19 have been rejected under 35 U.S.C. § 102(a) as allegedly anticipated by GenBank Accession Nos: AB035137 (August 9, 2000) and AF296825 (August 23, 2000). Office Action at page 5. In particular, the Examiner alleges that both of the cited references have 96.2% identity with SEQ ID NO: 1, "thus meeting the

limitation of 'sharing' and identity somewhere within the sequence of SEQ ID NO: 1." *Id.* Applicants respectfully disagree with this rejection.

In order to sustain a 35 U.S.C. § 102 rejection, the Examiner must establish that the subject matter of the instant claims was described in a printed publication in this or a foreign country, before the invention thereof by applicant. Applicants submit that the cited GenBank references do not qualify as prior art. The present application is a continuation of U.S. Patent Application Serial No. 09/229,413, filed January 12, 1999. Therefore, the present application is, at a minimum, entitled to the filing date of January 12, 1999. *See*, Preliminary Amendment and PTO form PTO/SB/05 filed August 6, 2001. The cited GenBank references are dated August 9, 2000 (AB035137) and August 23, 2000 (AF296825). As such, claims 15-19 are not anticipated by either GenBank accession number AB035137 or AF296825 cited by the Examiner. Reconsideration and withdrawal of the 35 U.S.C. § 102(a) rejections are respectfully requested.

Claims 15-19 have also been rejected under 35 U.S.C. § 102(b) as allegedly anticipated by GenBank Accession No. D30807 (March 8, 1995). Office Action at pages 5. In particular, the Examiner alleges that "D30807 and SEQ ID NO: 1 have an identity of 83.4%, thus meeting the limitation of 'sharing' and identity somewhere within the sequence of SEQ ID NO: 1." *Id.* Applicants respectfully traverse this rejection.

"It is axiomatic that for prior art to anticipate under § 102 it has to meet every element of the claimed invention." *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986). Further, "an anticipation rejection requires a showing that each limitation of a claim must be found in a single reference, practice, or device." *In re Donohue*, 766 F.2d 531, 226 U.S.P.Q. 619 (Fed. Cir. 1985). Whatever GenBank Accession D30807 teaches, it does not disclose SEQ ID NO: 1 or complete complement thereof. Nor does it disclose a nucleic acid molecule having between 90% and 100% identity with a nucleic acid molecule of SEQ ID NO: 1 or complete

complement thereof. Absent a teaching of each and every element of the claim, *i.e.*, SEQ ID NO: 1, the reference cited by the Examiner does not anticipate claims 15-19 and the rejection should be withdrawn.

Claims 15-19 have been further "rejected under 35 U.S.C. § 102(b) as being anticipate by AF115821 (November 15, 1999)." Office Action at page 6. Applicants respectfully submit that AF115821 does not qualify as prior art against the present application.

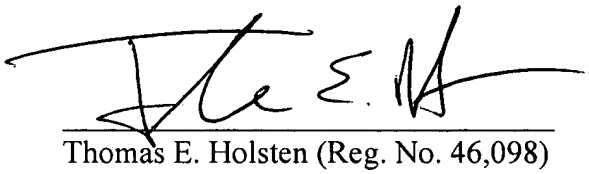
As argued above, to sustain a 35 U.S.C. § 102 rejection, the Examiner must establish that the subject matter of the instant claims was described in a printed publication in this or a foreign country, before the invention thereof by applicant. Applicants submit that the cited GenBank references do not qualify as prior art. The present application is a continuation of U.S. Patent Application Serial No. 09/229,413, filed January 12, 1999 and is therefore, at a minimum, entitled to that filing date. *See*, Preliminary Amendment and PTO form PTO/SB/05 filed August 6, 2001. As such, claims 15-19 are not anticipated by AF115821 cited by the Examiner. Reconsideration and withdrawal of the 35 U.S.C. § 102(b) rejections are respectfully requested.

Accordingly, for at least the foregoing reasons, the rejections of claims 15-19 under 35 U.S.C. §§ 102 (a) and (b) are improper. Reconsideration and withdrawal of these rejections are respectfully requested.

Conclusion

In view of the foregoing remarks, Applicants respectfully submit that the present application is now in condition for allowance, and notice of such is respectfully requested. The Examiner is encouraged to contact the undersigned should any additional information be necessary for allowance.

Respectfully submitted,



Date: November 23, 2004

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